DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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JUN 27 1995

Dear Sir/Madam:

This is the ninth in a series of policy letters regarding the implementation of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA), which was signed into law on November 16, 1988.

We are introducing a revised policy statement (refer to the attachment) which addresses our continuing implementation of GADPTRA. The policy statement is entitled Environmental Review of Generic Animal Drugs.

The policy statement is a revision of the policy statement of the same title which was issued in our second policy letter dated June 7, 1989. The second policy letter required the submission of an environmental assessment (EA) for the finished and bulk manufacturing site(s) for the production of the product. The revised policy eliminates the routine requirement for an EA and requires the submission of a request for categorical exclusion under 21 CFR 25.24(d)(1) for an ANADA.

We welcome comments and questions on the policy statement from all interested parties. If any changes are made, the revised statement will be placed on public display, and a notice of its availability will be published in the *Federal Register*.

Comments on the policy statement should be addressed to:

Dockets Management Branch
Docket No. 88N 0394
HFA-305, Room 4-62
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We will continue to announce the availability of future policy statements regarding the implementation of GADPTRA.

Sincerely yours,

Stephen Sundlof, D.V.M., Ph.D.
Director, Center for
Veterinary Medicine

Attachment

Environmental Review of Generic Animal Drugs

The National Environmental Policy Act (NEPA) requires that the Food and Drug Administration consider in its decision making, and disclose to the public, the environmental impacts that may be expected from proposed actions. The FDA's procedures for implementing NEPA are contained in 21 CFR Part 25. This discussion provides supplemental information specific to the Center's environmental policy regarding the implementation of the Generic Animal Drug and Patent Term Restoration Act (GAPTRA).

Although 21 CFR 25.24(d)(1) provided a categorical exclusion from preparing an environmental assessment (EA) for certain previously approved animal drugs, CVM announced, in the second policy letter dated June 7, 1989, that it would require that applicants ordinarily provide as part of each abbreviated new animal drug application (ANADA), adequate information to objectively determine and verify the potential environmental impacts of the manufacture, but not the use, of the generic product. To meet this requirement, sponsors were required to organize the environmental information in the environmental assessment (EA) format that was provided as an attachment to the policy letter. The EA content and format, was based on the abbreviated EA formats for certain other classes of animal drugs contained in 21 CFR 25.31a(b)(4). The EA's are available for public review at the time of approval of ANADA's.

This cautious approach was taken because ANADA's were anticipated to usually provide for new bulk drug and final product manufacturing sites that are controlled by different sponsors than those described in the pioneer new animal drug applications. The EA requirement was designed to examine this difference in manufacturing sites. Information about potential environmental impacts from the use of the product was not required because introduction of the drug into the environment from its use as a generic generally would not alter the drug already present in the environment as a result of approval of a pioneer.

Since the June 7, 1989 policy letter, CVM has reviewed over 100 EAs for generic animal drug products. After reviewing the EAs, with few exceptions, the Center has prepared Findings of No Significant Impact (FONSI) for the manufacturing of the generic animal drug products. In those cases, where the EAs were inadequate, they were inadequate because of incorrect formatting or because of missing information for the applicable environmental requirements. On few occasions, the lack of information resulted in the sponsors going back to the Federal, State or local environmental offices that had responsibility for the site of manufacturing, correcting manufacturing processes to comply with the environmental requirements, and obtaining the proper documentation. In no case has CVM determined that a significant impact could result from the manufacturing of a generic animal drug product. Additionally, no mitigation of potential environmental impacts has been necessary.

Because CVM has not identified any significant environmental impacts from the manufacturing of generic animal drug products, the caution that CVM exercised is no longer necessary. Therefore, an EA will no longer routinely be required for ANADAs. Instead, CVM will categorically exclude ANADAs from preparation of an EA under 25.24(d)(1).

Categorical exclusions are provided for actions that do not individually or cumulatively have a significant effect on the human environment. Neither an environmental assessment nor an environment impact statement is required (see 40 CFR 1508.4) for such actions. As indicated above, since the June 7, 1989 policy letter, CVM has found no instance where significant environmental effects were expected as a result of the manufacture of a generic animal drug product. Therefore, a categorical exclusion is the more appropriate route for CVM to meet NEPA requirements for generic animal drug applications.

Categorical exclusions for certain new animal drug applications (NADAs) already exist under 21 CFR 25.24(d)(1). The categorical exclusion applies if the NADA meets the specified criteria that the drug product will not be administered at a higher dosage level, for a longer duration or for a different indication then were previously in effect. An ANADA is merely an abbreviated form of an NADA. Therefore, when an ANADA meets the specified criteria, the ANADA will usually qualify for a categorical exclusion under 21 CFR 25.24(d)(1).

Meeting the criteria for a categorical exclusion does not guarantee that an action will be categorically excluded. The categorical exclusion in 21 CFR 25.24(d)(1) already provides that if data establish that at the expected level of exposure the substance may be toxic to the environment, CVM will require an EA. Furthermore, under 21 CFR 25.23(b), if data establish that the proposed action may significantly affect the environment, CVM will require an EA.

CVM is revising its policy regarding the environmental requirement for ANADAs. An ANADA submitted for an animal drug product must ordinarily include a request for categorical exclusion from the preparation of an EA under 21 CFR 25.24(d)(1). The Center will review the request for categorical exclusion and determine whether the criteria listed for the exclusion are met. If the criteria are met, and the agency has no information available to it to establish that the proposed action may significantly affect the environment, the categorical exclusion will be granted. If the Center finds, or a sponsor determines, that the categorical exclusion does not apply, or information indicates that the proposed action may significantly affect the environment, then an EA will be required for the action.